UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE GENZYME CORP. SECURITIES LITIGATION	)	Consolidated Case No. 09-cv-11267 (GAO)
	)	**Leave to file granted on January 18, 2012**

LEAD PLAINTIFFS' NOTICE OF SUPPLEMENTAL AUTHORITY IN SUPPORT OF THEIR OPPOSITION TO DEFENDANTS' MOTIONS TO DISMISS

Lead Plaintiffs respectfully file this notice of supplemental authority to advise the Court of several relevant decisions involving securities fraud claims against drug companies which were issued after briefing closed in this action, including cases involving the inferences that can be drawn where drug companies have not disclosed Form 483s (or the nature and extent of the CGMP problems that caused the FDA to issue them), or where drug companies have accompanied partial disclosure of problems with false assurances that any problems have been fixed or are capable of being quickly remedied. As summarized in Plaintiffs' Opposition Brief (Dkt. No. 68) ("Opp. To MTD") and confirmed by the cases below, even partial disclosures are plainly actionable where they amount to little more than the minimum necessary to maintain a false veneer of candor that continues to conceal the underlying truth.

1. *Wilkof v. Caraco Pharm. Labs., Ltd.*, 2010 WL 4184465 (E.D. Mich. Oct. 21, 2010) (Ex. A) – The court sustained allegations that the defendants falsely represented their compliance with CGMP, and knowingly or recklessly claimed to have rectified any problems after concerns about their CGMP compliance became public. *Id.* at *1, *10. The court held *inter alia* (a) that the defendants' undisclosed receipt of Form 483s from the FDA put them on notice of the extent of the deficiencies, *id.* at *5; (b) that the Form 483s should not be deemed immaterial merely because they might have been nominally available to members of the public, *id.* at *4; (c) that the defendants' disclosures of *some* deficiencies while failing to speak *fully and*

truthfully about the extent of the problems was actionable, *id.* at *4; and (d) that the temporal proximity between (i) the defendants' false assurances of compliance with CGMP and (ii) various government actions contrary to such assurances helped support a strong inference of scienter, *id.* at *5. Finally, the court concluded that any forward-looking statements were not insulated by the PSLRA's safe harbor, because the defendants' cautionary language could not be meaningful absent disclosure of the extent of their noncompliance with CGMP. *Id.* at *9.

This case further supports Lead Plaintiffs' claims here that:

(1) Defendants' receipt of the October 2008 Form 483 put them on notice of the deficiencies at its flagship Allston plant, and rendered their assurances of imminent Lumizyme approval materially false or misleading (Opp. to MTD at 30, 41-42, 52);

(2) Defendants' later combination of partial disclosures and false assurances downplaying GCMP compliance concerns were actionable (*id.* at 34-42, 45-46);

(3) Defendants' scienter may be inferred *inter alia* from (a) the fact that Allston was *shut down* by a contamination outbreak in June 2009 just after Defendants had assured investors that CGMP problems had been fixed, (b) the FDA's own later conclusion that Defendants had failed to take even basic steps to fix problems that FDA had identified as early as October 2008, and (c) Defendants' own private admissions to the FDA *during the Class Period* (and shortly before Allston would suffer yet another crippling contamination outbreak) that Allston's problems were actually "systemic" (*id.* at 51-53); and

(4) Defendants' "cautionary language" was insufficient to immunize them from liability for misstatements and omissions concerning then-existing conditions at Genzyme (*id.* at 71-75).

2. *In re MannKind Sec. Actions*, 2011 WL 6327089 (C.D. Cal. Dec. 16, 2011) (Ex. B) – The court sustained allegations that defendants misled investors about the likelihood that their new drug product would be approved by the FDA. Citing numerous cases, the court concluded that "[w]hen the FDA tells a company about the problems with a product, and the company nonetheless continues to make confident statements about the product, courts have inferred [both] scienter and falsity." *Id.* at *12. The court also accepted the inference that the defendants had misled investors about its discussions with the FDA, finding it unlikely that the

FDA would have told defendants that their clinical trial plan was sufficient for obtaining FDA approval (as defendants communicated to the public) only to change its mind a few months later. *Id.* at *10. The court agreed that knowledge of the problems could be inferred from the defendants' senior positions and the drug's critical importance to the company, *id.* at *15-16, and also held that boilerplate warnings of possible non-approval were not sufficient to immunize defendants from liability for failing to adequately disclose known problems. *Id.* at *18.

MannKind further supports Lead Plaintiffs' claims that (1) Defendants misled investors by assuring them Lumizyme would be approved while simultaneously withholding information about the true extent of CGMP problems at Allston (where Lumizyme was to be produced) and defendants' purported "efforts" to correct those problems, Opp. to MTD at 30-34, 45-46; (2) Defendants falsely assured investors that the FDA had told them that the CGMP problems at Allston had been adequately addressed, *id.* at 33, 55-56; (3) Defendants' senior positions in the Company and the vital importance of Allston supported a strong inference of scienter, *id.* at 56-58; and (4) Defendants' boilerplate cautionary language was not sufficient to trigger safe harbor protection for any forward-looking statements, *id.* at 71-75.

3. *Shapiro v. Matrixx Initiatives, Inc.*, 2011 U.S. Dist. LEXIS 111159 (D. Ariz. Sept. 26, 2011) (Ex. C) – In a follow-on case to the Supreme Court's *Matrixx Initiatives, Inc. v. Siracusano*, 131 S. Ct. 1309 (2011), the district court sustained allegations that the defendants misled the public about the dangers posed by Zicam (a drug manufactured by Matrixx) by failing to disclose customer complaints. The court rejected defendants' argument that their disclosure of *some* of the problems negated an inference of scienter with respect to the information they continued to withhold, *id.* at *15-18, and also relied in part on the existence of an FDA Form 483 to sustain the plaintiffs' allegations, *id.* at *5. This case further supports Plaintiffs' arguments that (1) Defendants' belated partial disclosure of *some* FDA concerns (such as those contained in

the 2009 Warning Letter that would promptly be published anyway) does *not* negate the inference of their scienter with respect to adverse information that they continued to withhold, Opp to MTD at 64-65; and that (2) the contents of the October 2008 Form 483 (*inter alia*) provide a sufficient basis for alleging the existence of material (and indeed "systemic") problems at Allston throughout the Class Period that were never adequately disclosed, *id.* at 36-42.[1]

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Respectfully submitted,

/s/ Bryan A. Wood
Bryan A. Wood, BBO # 648414
BERMAN DEVALERIO
One Liberty Square
Boston, MA 02109
bwood@bermandevalerio.com
Telephone: (617) 542-8300
Facsimile: (617) 542-1194

Liaison Counsel for Lead Plaintiffs

Jay W. Eisenhofer
Megan D. McIntyre
Diane Zilka
GRANT & EISENHOFER P.A.
123 Justison St.
Wilmington, DE 19801
Telephone: (302) 622-7000
Facsimile: (302) 622-7100

William C. Fredericks
Ann M. Lipton
BERNSTEIN LITOWITZ BERGER
& GROSSMANN LLP
1285 Avenue of the Americas
New York, NY 10019
Telephone: (212) 554-1400
Facsimile: (212) 554-1444

Co-Lead Counsel for Lead Plaintiffs

[1] The significance of last spring's Supreme Court decision in *Matrixx*, notably with respect to issues of materiality and scienter, is the subject of a separate Notice of Supplemental Authority (Dkt No. 83) and response by Defendants (Dkt. No. 86).

CERTIFICATE OF SERVICE

I, Bryan A. Wood, hereby certify that this document, filed through the ECF system, will be sent electronically to the registered participants as identified on the Notice of Electronic Filing, and paper copies will be sent to those indicated as nonregistered participants by first class mail on January 18, 2012.

Dated: January 18, 2012

/s/ Bryan A. Wood
Bryan A. Wood